

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 30 July 2001 (30.07.01)	
International application No. PCT/JP00/06852	Applicant's or agent's file reference P757PCT
International filing date (day/month/year) 03 October 2000 (03.10.00)	Priority date (day/month/year) 18 October 1999 (18.10.99)
Applicant OHTOMO, Kazumi et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 17 April 2001 (17.04.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Maria Kirchner Telephone No.: (41-22) 338.83.38
--	---

World Intellectual Property Organization
International Bureau



(43) International Publication Date
26 April 2001 (26.04.2001)

PCT

(10) International Publication Number
WO 01/28522 A3

- (51) International Patent Classification⁷: **A61K 9/127**, 31/436
- (21) International Application Number: **PCT/JP00/06852**
- (22) International Filing Date: 3 October 2000 (03.10.2000)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
11/295834 18 October 1999 (18.10.1999) JP
- (71) Applicant (for all designated States except US): **FUJISAWA PHARMACEUTICAL CO., LTD.** [JP/JP]: 4-7, Doshomachi 3-chome, Chuo-ku, Osaka-shi, Osaka 541-8514 (JP).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **OHTOMO, Kazumi** [JP/JP]: c/o Fujisawa Pharmaceutical Co., Ltd., 4-7, Doshomachi 3-chome, Chuo-ku, Osaka-shi, Osaka 541-8514 (JP). **KONNO, Hajime** [JP/JP]: c/o Fujisawa Pharmaceutical Co., Ltd., 4-7, Doshomachi 3-chome, Chuo-ku, Osaka-shi, Osaka 541-8514 (JP). **KASAI, Akihiro** [JP/JP]: c/o Fujisawa Pharmaceutical Co., Ltd., 4-7, Doshomachi 3-chome, Chuo-ku, Osaka-shi, Osaka 541-8514 (JP).
- (74) Agents: **KOTANI, Etsuji** et al.: Nichimen Building 2nd Floor, 2-2, Nakanoshima 2-chome, Kita-ku, Osaka-shi, Osaka 530-0005 (JP).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:
— with international search report
- (88) Date of publication of the international search report:
10 May 2002
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD FOR PRODUCING LIPOSOME PREPARATION

(57) Abstract: An object of the present invention is to provide a method for producing a liposome preparation having excellent rapid action and excellent redispersion into aqueous medium. The present invention provides a method for producing a liposome preparation by vacuum drying wherein liposome condensed solution, which is obtained by removing solvent from liposome solution, is subjected to vacuum drying without freezing while bubbling the condensed solution or after the condensed solution is bubbled.

WO 01/28522 A3

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P757PCT	<div style="display: flex; justify-content: space-between;"> <div style="text-align: center;">FOR FURTHER ACTION</div> <div style="font-size: small;">see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.</div> </div>	
International application No. PCT/JP 00/ 06852	International filing date (day/month/year) 03/10/2000	(Earliest) Priority Date (day/month/year) 18/10/1999
Applicant FUJISAWA PHARMACEUTICAL CO., LTD.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

= ☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/JP 00/06852

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/127 A61K31/436

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 92 22298 A (WU GUANLI ; UNGER EVAN C (US)) 23 December 1992 (1992-12-23) page 20, line 12 - page 21, line 2 examples 1,3 claims 1,2,28,45 ---	1-3,5,6, 9,10,12
X	WO 86 01103 A (LIPOSOME CO INC) 27 February 1986 (1986-02-27) page 8, line 1 - line 17 page 13, line 20 - line 26 example 1 claims 1,4,10,20,22 ---	1,5,6,9, 10,12
X	US 4 532 130 A (DJORDJEVICH LJUBOMIR ET AL) 30 July 1985 (1985-07-30) examples 1,3 claims 1,6,8,11 --- -/--	1,2,5,6, 9,12

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

19 July 2001

Date of mailing of the international search report

01/08/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Epskamp, S

INTERNATIONAL SEARCH REPORT

International Application No

JP 00/06852

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE WPI Section Ch, Week 199505 Derwent Publications Ltd., London, GB; Class B05, AN 1995-032407 XP002164972 & JP 06 315623 A (CHIBA SEIFUN KK), 15 November 1994 (1994-11-15) abstract	1,5,6,9, 12
X	EP 0 658 344 A (FUJISAWA PHARMACEUTICAL CO) 21 June 1995 (1995-06-21) page 6, line 54 - line 55 examples claims & WO 93 08802 A (FUJISAWA PHARMACEUTICAL CO.) 13 May 1993 (1993-05-13) cited in the application	12

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

JP 00/06852

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9222298	A	23-12-1992	AU 667672 B	04-04-1996
			AU 2023892 A	12-01-1993
			CA 2110490 A	23-12-1992
			EP 0660714 A	05-07-1995
			JP 6508617 T	29-09-1994
			US 5469854 A	28-11-1995
			US 5580575 A	03-12-1996
			US 5585112 A	17-12-1996
			US 5542935 A	06-08-1996
			US 5773024 A	30-06-1998
			US 5733572 A	31-03-1998
			US 5922304 A	13-07-1999
			US 5705187 A	06-01-1998
			US 5715824 A	10-02-1998
			US 5770222 A	23-06-1998
			US 6088613 A	11-07-2000
			US 5656211 A	12-08-1997
			US 5853752 A	29-12-1998
			US 6146657 A	14-11-2000
			US 5935553 A	10-08-1999
			US 6039557 A	21-03-2000
			US 6071495 A	06-06-2000
WO 8601103	A	27-02-1986	US 4880635 A	14-11-1989
			AT 96311 T	15-11-1993
			AT 96310 T	15-11-1993
			AT 149347 T	15-03-1997
			AT 149346 T	15-03-1997
			CA 1270197 A	12-06-1990
			CA 1270198 A	12-06-1990
			CA 1283604 A	30-04-1991
			CA 1294548 A	21-01-1992
			CA 1305054 A	14-07-1992
			DE 3587639 D	02-12-1993
			DE 3587639 T	24-03-1994
			DE 3587640 D	02-12-1993
			DE 3587640 T	31-03-1994
			DE 3588146 D	10-04-1997
			DE 3588146 T	09-10-1997
			DE 3588148 D	10-04-1997
			DE 3588148 T	09-10-1997
			EP 0191824 A	27-08-1986
			EP 0190315 A	13-08-1986
			EP 0562641 A	29-09-1993
			EP 0561424 A	22-09-1993
			ES 545955 D	01-12-1986
			ES 8701516 A	01-03-1987
			ES 552076 D	16-04-1987
			ES 8704755 A	01-07-1987
			HK 1007494 A	16-04-1999
			HK 1007501 A	16-04-1999
			IE 68686 B	10-07-1996
			IL 76010 A	18-01-1990
			JP 2847065 B	13-01-1999
			JP 9020652 A	21-01-1997
			JP 2574999 B	22-01-1997
			JP 7145041 A	06-06-1995
			JP 2572553 B	16-01-1997

INTERNATIONAL SEARCH REPORT

Information on patent family members

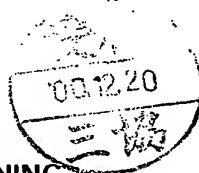
International Application No

P 00/06852

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 8601103 A		JP 7165560 A	27-06-1995
		JP 2572554 B	16-01-1997
		JP 7145042 A	06-06-1995
		JP 2579441 B	05-02-1997
		JP 7145043 A	06-06-1995
		JP 2579442 B	05-02-1997
		JP 7145040 A	06-06-1995
		JP 7112968 B	06-12-1995
		JP 62500101 T	16-01-1987
		JP 8018973 B	28-02-1996
		JP 62500102 T	16-01-1987
		PT 80926 A, B	01-09-1985
		US 5578320 A	26-11-1996
		WO 8601102 A	27-02-1986
		US 5077056 A	31-12-1991
<hr/>			
US 4532130 A	30-07-1985	AU 8760682 A	02-02-1983
		EP 0082877 A	06-07-1983
		WO 8300089 A	20-01-1983
<hr/>			
JP 6315623 A	15-11-1994	NONE	
<hr/>			
EP 0658344 A	21-06-1995	AT 188378 T	15-01-2000
		DE 69230541 D	10-02-2000
		DE 69230541 T	24-08-2000
		DK 658344 T	17-04-2000
		GR 3032319 T	27-04-2000
		KR 253492 B	01-05-2000
		CA 2122344 A	01-05-1993
		ES 2140419 T	01-03-2000
		WO 9308802 A	13-05-1993
		US 5817333 A	06-10-1998
<hr/>			

PCT COOPERATION TREATY

PCT



**NOTIFICATION CONCERNING
SUBMISSION OR TRANSMITTAL
OF PRIORITY DOCUMENT**

(PCT Administrative Instructions, Section 411)

From the INTERNATIONAL BUREAU

To:

KOTANI, Etsuji
Sumisei Naniwasuji Honmachi
Building 3-2,
Utsubohonmachi 2-chome
Nishi-ku, Osaka-shi
Osaka 550-0004
JAPON

Date of mailing (day/month/year) 24 November 2000 (24.11.00)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference P757PCT	
International application No. PCT/JP00/06852	International filing date (day/month/year) 03-October-2000 (03.10.00)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 18 October 1999 (18.10.99)
Applicant FUJISAWA PHARMACEUTICAL CO., LTD. et al	

- The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
- This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
- An asterisk(*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed to Rule 17.1(c)** which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
- The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed to Rule 17.1(c)** which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
18 Octo 1999 (18.10.99)	11/295834	JP	17 Nove 2000 (17.11.00)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Khemaïs BRAHMI

Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

NOTICE INFORMING THE APPLICANT OF THE
COMMUNICATION OF THE INTERNATIONAL
APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

From the INTERNATIONAL BUREAU

To:

KOTANI, Etsuji
Nichimen Building 2nd Floor
2-2, Nakanoshima 2-chome
Kita-ku, Osaka-shi, Osaka 530-0005
JAPON

Date of mailing (day/month/year) 26 April 2001 (26.04.01)		IMPORTANT NOTICE	
Applicant's or agent's file reference P757PCT			
International application No. PCT/JP00/06852	International filing date (day/month/year) 03-October-2000 (03.10.00)	Priority date (day/month/year) 18 October 1999 (18.10.99)	
Applicant FUJISAWA PHARMACEUTICAL CO., LTD. et al			

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
AU,KP,KR,US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AE,AG,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,BZ,CA,CH,CN,CR,CU,CZ,DE,DK,DM,DZ,EA,EE,EP,ES,
FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,
MN,MW,MX,MZ,NO,NZ,OA,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,
The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
26 April 2001 (26.04.01) under No. WO 01/28522

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer J. Zahra Telephone No. (41-22) 338.83.38
--	---


PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P757PCT		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP00/06852	International filing date (day/month/year) 03/10/2000	Priority date (day/month/year) 18/10/1999	
International Patent Classification (IPC) or national classification and IPC A61K9/127			
Applicant FUJISAWA PHARMACEUTICAL CO., LTD.			

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>	
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application 	

Date of submission of the demand 17/04/2001	Date of completion of this report 06.02.2002
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Lindner, A Telephone No. +49 89 2399 8640



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP00/06852

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-34 as originally filed

Claims, No.:

1-12 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/JP00/06852

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims 1-11
	No: Claims 12
Inventive step (IS)	Yes: Claims
	No: Claims 1-11
Industrial applicability (IA)	Yes: Claims 1-12
	No: Claims

**2. Citations and explanations
see separate sheet**

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:
D1: WO 92 22298 A (WU GUANLI ;UNGER EVAN C (US)) 23 December 1992 (1992-12-23)
D2: WO 86 01103 A (LIPOSOME CO INC) 27 February 1986 (1986-02-27)
~~D3: US-A-4 532 130 (DJORDJEVICH LJUBOMIR ET AL) 30 July 1985 (1985-07-30)~~
D4: DATABASE WPI Section Ch, Week 199505 Derwent Publications Ltd., London, GB; Class B05, AN 1995-032407 XP002164972 & JP 06 315623 A (CHIBA SEIFUN KK), 15 November 1994 (1994-11-15)
2. All of documents D1 to D4 relate to a method for producing liposomes wherein a liposome solution is subjected to vacuum drying without freezing (D1: p. 20, l. 12 - p. 21, l. 2; examples 1-3; claims; D2: p. 8, l. 1-17; p. 13, l. 20-26; example 1; claims 1, 4, 10, 20, 22; D3: examples 1 and 3; claims 1, 6, 8, 11; D4; whole document). The step of first removing solvent separately is not specifically disclosed in D1-D4.
3. The subject-matter of claim 12 is not novel over any of documents D1-D4 (Article 33(2) PCT). In this context it is noted that the separate removal of solvent does not have any influence on the final product, all the more so as no lipid or solvent concentrations are given.
4. The subject-matter of claims 1-11 does not involve an inventive step over any of documents D1-D4. Thus, the method as claimed in present claim 1 encompasses the situation that a very diluted liposome solution is first concentrated for practical reasons before it is subjected to vacuum drying. Nothing inventive can be seen in such a step.